February 19, 2022

Well-Life Healthcare Limited
Jenny Hsieh
Official Correspondent
6F., No.168, Lide St., Jhonghe District
New Taipei City, 235
Taiwan

Re: K213091
Trade/Device Name: Well-Life TENS/EMS/Heating Stimulator
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: NUH, NGX, IRT
Dated: January 17, 2022
Received: January 21, 2022

Dear Jenny Hsieh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Pamela Scott
Assistant Director, Neuromodulation Psychiatry Devices
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213091

Device Name
Well-Life TENS/EMS/Heating Stimulator

Indications for Use *(Describe)*
The WL-2405K+ is a digital electrical and heat stimulator for active treatment application as the following:

TENS can be used for the following applications:

- For temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, upper extremities (arm) and lower extremities (leg) due to strain from exercise or normal household and work activities.

EMS can be used for the following applications:

- For healthy adults for the stimulation of healthy muscles in order to improve or facilitate muscle performance.

Heat Mode:

- Heat can be used for temporary relief of minor aches and pains.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Well-Life Healthcare Limited

Section 5

510(k) Summary

Well-Life Healthcare Limited

510(K) Summary

1. Type of Submission: Traditional

2. Preparation date: 17th September, 2021
   Revision date: 19th February, 2022

3. Submitter: Well-Life Healthcare Ltd.
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   Phone: +886-2-22266981
   Fax: +886-2-22266965
   Contact: Jenny Hsieh
   (jenny@welllifehealthcare.com.tw)
   Registration number: 3006850006

4. Identification of the device:

Device Name:	Well-Life TENS/EMS/Heating Stimulator
Common or usual name:	Electrical Heating Stimulator
Device Model:	WL-2405K+
Classification product code:	NUH
Subsequent product code:	NGX, IRT
Device Classification:	II
Regulation Number:	1) 882.5890 2) 890.5850 3) 890.5740
Regulation description:	1) Transcutaneous electrical nerve stimulator for pain relief 2) Powered muscle stimulator 3) Power heating pad
Review panel:	1) Neurology 2) Physical Medicine 3) Physical Medicine

5. Identification of the Predicate Device:

Primary Predicate Device (K203574)

Device Name:	HIVOX OTC Electrical Stimulator
Common or usual name:	Electrical Heating Stimulator
Device Model:	EM-59-2
Classification product code:	NUH
Subsequent product code:	NGX, IRT
Device Classification:	II
Regulation Number:	1) 882.5890 2) 890.5850 3) 890.5740
Regulation description:	1) Transcutaneous electrical nerve stimulator for pain relief 2) Powered muscle stimulator 3) Power heating pad
Review panel:	1) Neurology 2) Physical Medicine 3) Physical Medicine

Secondary Predicate Device (K172809)

Device Name:	Otc combo tens/ems system
Common or usual name:	OTC Combo TENS/EMS System
Device Model:	WL-2405G, WL-2405H
Classification product code:	NUH
Subsequent product code:	NGX NYN
Device Classification:	II
Regulation Number:	1) 882.5890 2) 890.5850
Regulation description:	1) Transcutaneous electrical nerve stimulator for pain relief 2) Powered muscle stimulator
Review panel:	1) Neurology 2) Physical Medicine

6. Intended Use and Indications for use of the Subject Device:

The WL-2405K^{+} is a digital electrical and heat stimulator for active treatment application as the following.

TENS can be used for the following applications:

- For temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, upper extremities (arm) and lower extremities (leg) due to strain from exercise or normal household and work activities.

EMS can be used for the following applications:

- For healthy adults for the stimulation of healthy muscles in order to improve or facilitate muscle performance.

Heat Mode:

- Heat can be used for temporary relief of minor aches and pains.

7. Description of the Device:

Well-Life OTC TENS/EMS/Heating Stimulator Device, Model no. WL-2405K^{+} provides a combination of transcutaneous electrical nerve stimulation (TENS) for temporary relief of pain associated with sore and aching muscles due to strain from exercise, normal household chores and work related activities, Electrical Muscle Stimulator (EMS) can be used to stimulate healthy muscles in order to facilitate muscle performance, relax muscle spasms, prevent or retard disuse atrophy, re-educate muscles and to maintain or increase the range of motion, Heat can be used in warming the muscle for soothing comfort.

The stimulator generates the output current specified as the input of controller. The output port transmits the output current & heat to the electrode, which is attached to the user's skin ；with the combination of the main device parts, the device can be placed on the treatment locations as recommended in the user manual for temporary relief of pain associated with sore and aching muscles in the low back, upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities, and to be used to stimulate healthy muscle in order to improve and facilitate muscle performance.

The device includes several operating elements, such as the ON/OFF button, intensity increase button, and intensity decrease button, and could be attached and detached to electrodes. The device has multiple program modes of different pulse frequencies, covering TENS/EMS and heat. While used in the heating mode, the device is coupled with electronically controlled electrodes to provide automatic thermal heat to the skin with the maximum temperature of 43℃.
For the heating cycle, the temperature will get to 43 degree Celsius in 130 seconds after turning on the heating mode, and when it reaches 43 degree Celsius then it will cool down to body temperature for 20 seconds, then back to 43 degree Celsius for 20 seconds , the cycle will continue for 15 minutes.

The device could be operated through its buttons to manually realize its functions, such as turning on/off and increasing/decreasing intensity, providing heat/temperature. Channel 1 can provide electrical stimulation signal, such as TENS/EMS, and it can only be performed by connecting an electrode and wire dedicated to electrical stimulation. Channel 2 can provide heat treatment, and it can only be carried out by connecting heat-exclusive electrode and wires. The exclusive accessories used for electrical stimulation or thermotherapy are marked by color to prevent misuse by the user. If you accidentally use it incorrectly, there will be a protective mechanism in the device to prevent it from operating and causing harm.

8. Statement of conformity

List of FDA-recognized voluntary consensus standards cited in this submission.

Recognition Number	Standard Designation Number and Date	Title Of Standard	Date Of Recognition
5-89	IEC 60601-1-6 Edition 3.1 2013-10	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	06/27/2016
5-114	IEC 62366-1 Edition 1.0 2015-02	Medical devices - Part 1: Application of usability engineering to medical devices	12/23/2016
2-258	ISO 10993-1 Fifth Edition 2018-08	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	01/14/2019
2-245	ISO 10993-5 Third Edition 2009-06-01	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	02/23/2016
2-174	ISO 10993-10 Third Edition 2010-08-01	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	07/26/2016
2-191	ISO 10993-12 Fourth Edition 2012-07-01	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials	07/26/2016
19-4	IEC 60601-1:2005, MOD	Medical electrical equipment- Part 1: General requirements for basic safety and essential performance	07/09/2014
19-8	IEC 60601-1-2 :2014	Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance -- Collateral Standard: Electromagnetic disturbances -- Requirements and tests	09/17/2018
19-14	IEC 60601-1-11 Edition 2.0 2015-01	Medical electrical equipment– Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	06/27/2016
17-16	IEC 60601-2-10 Edition 2.1 2016-04	Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators	06/27/2016

17-14	ANSI AAMI NS4:2013(R)2017	Transcutaneous Electrical Nerve Stimulators 2013(R)2017	01/14/2019
FDA Guidance	FDA-2020-D-0957	Shelf Life of Medical Devices	April 1991
14-497	ASTM F1980-16	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices	12/23/2016
FDA Guidance	Guidance for industry and FDA Staff	Guidance for the Content of Premarket Submissions for Software Contained in Medical Device	11/05/2005

9. Non-Clinical Testing Summary:

Non-clinical testing was conducted to verify that the subject devices met all design specifications, demonstrated safety based on current industry standards, and to demonstrate substantial equivalence to the predicate. The following tests were performed:

1) Usability Test

The applicable standard for the performance of Well-Life TENS/EMS/Heating Stimulator (model: WL-2405K^{+}) device is given on IEC/EN 60601-1-6:2016 & IEC/EN 62366:2016. Based on the verification & validation testing model WL-2405K^{+} is considered to meet the usability requirement as defined in the verification & validation test report.

2) Biocompatibility

The patient contacting materials of the Well-Life TENS/EMS/Heating Stimulator (model: WL-2405K^{+}) are the "electrode, cutaneous FDA Cleared (K082065)". The electrode is exactly the same as cleared with the Predicate Device OTC Combo TENS/EMS System (model: WL-2405G/H, K172809).Biocompatibility Patient contacting components are in compliance with ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process, including cytotoxicity (ISO 10993-5 Third Edition 2009-06-01), sensitization (ISO 10993-10 Third Edition 2010-08-01), irritation (ISO 10993-10 Third Edition 2010-08-01) and Sample preparation and reference materials (ISO 10993-12 Fourth Edition 2012-07-01)

3) Electromagnetic Compatibility and Electrical Safety

The applicable standard for the electric safety of Well-Life TENS/EMS/Heating Stimulator (model: WL-2405K^{+}) is given on IEC 60601-1 or ANSI/AAMI ES

60601-1. The representative Well-Life TENS/EMS/Heating Stimulator (model: WL-2405K^{+}) is tested by accredited test laboratory. The following electric safety tests are performed. They are 1. ANSI/AAMI ES 60601-1 test, 2. IEC 60601-1-11 test and 3. Li-ion safety test. After evaluation, the results meet the requirement of IEC 60601-1 standard: Ed 3.

4) Performance Testing Bench testing was performed to verify the performance to specifications of the proposed device and included the following:
The applicable standard for the performance of Well-Life TENS/EMS/Heating Stimulator (model: WL-2405K^{+}) device is given on IEC 60601-2-10. The representative Well-Life TENS/EMS/Heating Stimulator (model: WL-2405K^{+}) is tested by accredited test laboratory. After test, the result meets the requirement of IEC 60601-2-10.

5) Shelf Life Test
To demonstrate the adequacy of the shelf life, the recommended study process for the similar product released on guidance document FDA-2020-D-0957 "Shelf Life of Medical Devices" and ASTM F1980-16 "Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices "is followed. After test and study, basically the shelf life for The Well-Life TENS/EMS/Heating Stimulator (model: WL-2405K^{+}) is regard as 2 years.

6) Software Validation.
Generally, the applicable standard for the Software Validation Report of TENS/EMS/Heating stimulator device is given on "General Principles of Software Validation"; Final Guidance for Industry and FDA Staff Document issued on: 11/05/2005". In order to prove that the Software Validation for the submission model complies with the requirement of" General Principles of Software Validation", the representative sample WL-2405K^{+} is chosen for the systematic assessment of this standard. Based on the systematic assessment, some required test reports are provided. For the testing report of Software Validation.

9.1. Clinical Testing Summary

No clinical test data was used to support substantial equivalence.

10. Substantial Equivalence Determination:

10.1 Substantial Equivalence Comparison to Predicate Device

Elements of Comparison	Subject Device	Primary Predicate	Secondary Predicate	Remark
Company	Well-Life Healthcare Limited	HIVOX BIOTEK INC.	Well-Life Healthcare Limited	--
Device Name	Device name: Well-Life TENS/EMS/Heating Stimulator Model: WL-2405K+	Device name: HIVOX OTC Electrical Stimulator Model: EM59-1, EM59-2	Device name: OTC Combo TENS/EMS System Model: WL-2405G, WL-2405H	--
Product Code	NUH NGX IRT	NUH NGX IRT	NUH NGX NYN	Same
Regulation Number	882.5890	882.5890	882.5890	Same
Product K Number	Applying	K203574	K172809	--
OTC/Rx	OTC	OTC	OTC	
Indication for use	The WL-2405K+ is a digital electrical and heat stimulator for active treatment application as the following. TENS can be used for the following applications: ・For temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, upper extremities (arm) and lower extremities (leg) due to strain from exercise or normal household and work activities.	TENS: This function is designated to be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, upper extremities (arm) and lower extremities (leg) due to strain from exercise or normal household work activities.	TENS: It can be used for the temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, upper extremities (arm) and lower extremities (leg), due to strain from exercise or normal household	Note 1

	EMS can be used for the following applications: ・For healthy adults for the stimulation of healthy muscles in order to improve or facilitate muscle performance. Heat Mode: ・Heat can be used for temporary relief of minor aches and pains.	EMS: This function is designed to be used for stimulating healthy muscles in order to improve and facilitate muscle performance. SH: This function is designed to be used for temporary relief of minor aches and pains.	EMS: It can be used for the stimulation of healthy muscles in order to improve or facilitate muscle performance. SH: NA	
Power Source(s)	Rechargeable battery	Rechargeable battery	Rechargeable battery	Same
Function and Design	Electrical stimulation and heat	Electrical stimulation and heat	Electrical stimulation	Note 1
Heating Setting	Low and High	Low and High	NA	Note 1
Maximum Temperature Setting	43℃	43℃	NA	Note 1
Maximum Output Voltage (Vp, ±20%)	40V @500Ω 60V @2KΩ 88V @10KΩ	50V @500Ω 90V @2KΩ 125V @10KΩ	40V @500Ω 60V @2KΩ 88V @10KΩ	Note.2
Maximum Output Current (mAp, ±20%)	80mA @500Ω 30mA @2KΩ 8.8mA @10KΩ	100mA @500Ω 45mA @2KΩ 12.5mA @10KΩ	80mA @500Ω 30mA @2KΩ 8.8mA @10KΩ	Note.2
Pulse width (μs)	50 to 300	50 to 450	50 to 300	Note.2
Frequency (Hz)	1 to 100	1 to 150	1 to 100	Note.3
Maximum Phase Charge	TENS Mode: 260(max)	45	TENS Mode: 260(max)	Note.3

(µC @ 500Ω)	EMS Mode:260(max)		EMS Mode:260(max)	
Maximum Current Density (mA/cm² @ 500Ω)	TENS Mode: 0.067 EMS Mode:0.058	0.667	TENS Mode: 0.203 EMS Mode:0.095	Note.3
Maximum Power Density (W/cm² @ 500Ω)	TENS Mode: 0.0027 EMS Mode:0.0023	0.0046	TENS Mode:0.0081 EMS Mode:0.0038	Note.3
Output Signal	Electrical stimulation only Heat only	Electrical stimulation only Heat only Electrical stimulation + Heat simultaneously	Electrical stimulation only	Note 1
Method of Line Current Isolation	N/A (Internal power source)	N/A (Internal power source)	N/A (Internal power source)	SAME
Number of output Channels	2 Synchronous	2 Synchronous	2 Synchronous	SAME
Method of Channel Isolation	By electrical circuit and software	By electrical circuit and software	By electrical circuit and software	SAME
Software/Firmware/Microprocessor Control?	Yes	Yes	Yes	SAME
Automatic Overload Trip? **Automatic No-Load Trip?** **Automatic Shut Off?**	Yes	Yes	Yes	SAME
Patient Override Control?	Yes	Yes	Yes	SAME
Indicator Display **ON/OFF Status?** **Low battery?**	Yes	Yes	Yes	SAME

Intensity Level?				
Compliant with Voluntary Standards?	IEC60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-10	IEC60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-10	IEC60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-10	SAME
Compliant with 21 CFR 898?	Yes	Yes	Yes	SAME
Housing Materials and Construction	Plastic (ABS) enclosure	Plastic (ABS) enclosure	Plastic (ABS) enclosure	SAME
Waveform	Biphasic	Biphasic	Biphasic	SAME
Shape	Rectangular	Rectangular	Rectangular	SAME
Output Intensity	TENS: Level 0 to 25 EMS: Level 0 to 25 SH: Level LOW and HI	TENS: Level 0 to 50 EMS: Level 0 to 50 SH: Level LOW and HI	TENS: Level 0 to 25 EMS: Level 0 to 25	Note.4
Heating Level (℃)	LOW: up to 42 Level HI: up to 43	LOW: up to 41 Level HI: up to 43	N/A	Note.5

10.2 Comparison in Detail(s):

- **Note 1**

1) Indication for use, Function and Design, Heating Setting and Maximum Temperature Setting of the subject device are identical to the primary predicate device except the Output Signal.
2) The option for the Output Signal of primary predicate device is Electrical stimulation only, Heat only and Electrical stimulation + Heat simultaneously. The option for the Output Signal of subject device is Electrical stimulation only, Heat only. Since the option for the Output Signal of subject device is not more than primary predicate device and identical to the others, therefore can be considered as substantial equivalent.
3) Regard to the secondary predicated device, it is selected to be considered as substantial equivalent.in some electrical design of the subject device. Refer to Note 2, 3 and 4.
4) In TENS mode, the designed program in both subject device and primary predicate devices, from P1~P7 have the same output character. The secondary predicate device has an additional P8 mode for pain associated with arthritis. However, the subject device has not been found substantially equivalent to demonstrate safety and effectiveness for pain associated with arthritis and thus requires clinical evidence for this indication.

- **Note 2**

The Output Voltage and Current of the subject device is slightly lower than primary predicate device, but the intensity of heating is identical as 43℃, therefore can be considered as substantial equivalent

- **Note 3**

Since the Pulse width, Frequency, Maximum Phase Charge, Maximum Current Density, Maximum Power Density are the different design and specification in the different brand of electrical stimulator. Therefor the safety and effectiveness are the key points. The technical data of the output specifications of Pulse width (μs), Frequency (Hz), Maximum Phase Charge (μC @ 500Ω), Maximum Current Density (mA/cm^2 @ 500Ω), Maximum Power Density (W/cm^2 @ 500Ω) for the subject

device are shown as **Section 18.3 NS4 Report.** The result in comparing the subject device can be considered as substantial equivalent

- **Note 4**

The Intensity of the subject device is slightly lower than secondary predicate device, but the function and performance is similar, therefore can be considered as substantial equivalent

- **Note 5**

1) The High Heating Level (℃) of the subject device are identical to the primary predicate device.
2) The Low Heating Level (℃) of the primary predicate device is 41℃ and the subject device is 42℃. Since the Low Heating Level (℃) of subject device is not higher than primary predicate device and identical to the High Heating Level (℃) and the difference between 42℃ and 41℃ is minor , therefore can be considered as substantial equivalent.
3) Regard to the secondary predicated device, it is selected to be considered as substantial equivalent.in some electrical design of the subject device. Refer to Note 2, 3 and 4.

11. Conclusion:

Those 5 Notes indicated the differences among Subject devices, Primary and Secondary Predicate devices. Each note is explained respectively, especially in the safety, functions and performance which are applying in the Subject device are substantially equivalent with Primary Predicate devices. The Secondary predicated device is provided for being the reference in the technical design.

After Evaluation, the subject device has all feature of predicate devices. The few differences are explained and no matter with impact of the safety and effectiveness. Thus, the subject device is substantially equivalent with Predicate devices.